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No. 10-332

Supreme Court, U.S.
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In The

Supreme Court of the United States

MICHAEL J. McGUAN AND LILLIAN JOHNSON,

Petitioners,

v.

ENDOVASCULAR TECHNOLOGIES, INC., GUIDANT CORPORATION, ADVANCED CARDIOVASCULAR SYSTEMS, INC. AND ORIGIN MEDSYSTEMS, INC.,

Respondents.

On Petition For Writ Of Certiorari To The California Court Of Appeal Sixth Appellate District

REPLY BRIEF

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INTRODUCTION

The first half of Respondents' Brief in Opposition (hereinafter "Opp."), before addressing three arguments, is devoted to a lengthy Statement of the Case purportedly because Petitioners "studiously conflate arguments." Opp. 2. Notably, Respondents' statement fails to identify a single incident of conflation in the Petition for Certiorari (hereinafter "Pet."). It does, however, create the factual impression that Petitioners' parallel claims were not timely made or argued, and that the Sixth District's affirmation of the denial of Petitioners' motions to amend, on state law grounds, was necessary and warranted and based on an unambiguous state rule. Those factual impressions are all demonstrably false. *See* Argument I, below.

Respondents then make three arguments in opposition to a grant of certiorari.

(1) Respondents fail to provide any argument or bases for extending "fraud on the FDA" preemption under *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), to "parallel" claims of fraud on petitioners and their physicians. *See* Argument II, below.

(2) The Sixth District's Opinion is compelling and worthy of certiorari under Supreme Court Rule 10. *See* Argument IV, below.

(3) The Sixth District's affirmation of the denial of Petitioners' motions to amend on state law grounds was capricious, unwarranted and unnecessary, and

was based on an ambiguous state rule. *See* Argument III, below.

ARGUMENT

I. RESPONDENTS SEVERELY MISSTATE THE RECORD

A. Respondents Falsely Allege That Petitioners Failed To Timely Assert And Argue Their Parallel Claims

Respondents falsely assert that Petitioners, for the first time now, allege parallel claims of fraud on plaintiffs and their physicians. "Petitioners now seek to recast their proposed causes of action for fraud on the FDA as 'parallel claims' based on Respondents' alleged fraud on 'patients and their physicians.'" (Underlined emphasis added; Opp. 5). Respondents then assert that "Petitioners' new 'fraud on patients and physicians' argument was not presented to the trial court and was not raised in the Sixth District until Petitioners' reply briefs." (Underlined emphasis added; Opp. 6). They are wrong, and deceptive about it.

Petitioners' proposed amended complaints, lodged and served on May 12, 2008, contain allegations that Respondents violated federal regulations and that said violations misled the FDA, patients and their physicians. E.g., McGuan at App. 57-60. Even the Sixth District conceded, at App. 22, that "Plaintiffs sought to amend their complaints by adding causes of action for fraud on the FDA as well as fraud on

plaintiffs and their physicians based on defendants' failure to comply with federal regulations by providing accurate information to the FDA."

Although the proposed amended complaints do not label their new claims as "parallel," Petitioners presented "parallel claim" arguments to the trial court well before the hearing on their motions to amend, first on May 5 in opposition to Respondents' motions for summary judgment, then on May 12, 2008, in support of their motions to amend. Because of the importance of this false assertion, Petitioners' argument (Record 955) is set out here:

> An additional ground on which Defendant's Motion must be denied is that Plaintiff's state law claims parallel federal requirements. Most recently, in *Riegel* [*Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008)], the Court expressly noted that claims premised on a violation of federal requirements, or parallel claims, are not preempted. *Id.* The *Riegel* Court noted that its holding hinged upon the determination that the state common-law claims at issue imposed requirements "different from, or in addition to" the federal requirements imposed via the pre-market approval process. *Id.* The Court expressly reaffirmed its holding in *Lohr* [*Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996)], where a plurality of the Court held that states may provide traditional damages remedies for violations of common law duties so long as those duties parallel federal requirements. *Id.* [citation].

> The *Lohr* Court explained the nature of "parallel" claims in greater detail. . . .; *see also Wawrzynek* [*Wawrzynek v. Statprobe, Inc.*, No. 05-1342, 2007 U.S. Dist. LEXIS 80155 (E.D. Pa. 2007)], at *39-50 (upholding negligence and state law fraud claims); *see also Brooks v. Howmedica, Inc.*, 273 F.3d 785, 798 (8th Cir. 2001) "A claim of failure to comply with FDA regulations is not pre-empted by the MDA, since such a state claim imposes no requirement 'different from, or in addition to' any federal requirement.").

Even after receiving Petitioners' motions to amend their complaints, Respondents opposed the motions claiming that Petitioners alleged only "fraud on the FDA." (Record 2251-56). Petitioners thus slightly rephrased their parallel argument in their reply briefs (Record 2283), partially set out here:

> In addition, in *Riegel* [citation], the United States Supreme Court expressly noted that claims premised on a violation of federal requirements, or parallel claims, are not preempted. [citation]. The Court expressly reaffirmed its holding in *Lohr*, where a plurality of the Court held that states may provide traditional damages remedies for violations of common law duties so long as those duties parallel federal requirements. Id. [citation]. . . .

Petitioners made their first parallel claims argument to the Sixth District at page 30 of their opening

briefs, not in their reply briefs as Respondents assert. The beginning of the argument is partially set out here:

> In *Riegel* [citation], the United States Supreme Court expressly noted that claims premised on a violation of federal requirements, or parallel claims, are not preempted. [citation]. . . .

Finally, to further support their false theme of insufficient notice of Petitioners' parallel claims argument, Respondents refer to a comment by the Sixth District in footnote 6 of its opinion, about Petitioners' "Main Argument" being fraud on the FDA, as additional evidence that Petitioners argued fraud on the FDA in their opening brief, but not parallel claims. Opp. 7.

Petitioners advised this Court and Respondents (Pet. 15, fn. 5) that the content of the Sixth District's footnote 6 about Petitioners' "main issue" was not supported in the record. Respondents nevertheless, without reference to a page in the brief or context for the quote (and even though the Sixth District did not attribute the quote to the brief), assert that it was: "Petitioners' opening brief to the Sixth District identified the main issue on appeal. . . ." (Underlined emphasis added; Opp. 7).

Respondents' ignorance of Petitioners' parallel claims is feigned. Respondents' opposition partially quotes from Petitioners' proposed amended complaints

to evidence their false assertion that Petitioners claim fraud on the FDA. What they did not quote reveals their true knowledge. Respondents did not quote from paragraphs 90 through 93, which provide necessary background allegations for parallel claims (App. 69), and only partially quote from paragraphs 94 and 95 of Petitioner Johnson's proposed amended complaint. App. 70. Paragraphs 94 and 95 are set forth here, in their entirety to visually demonstrate Respondents' careful inclusion of the allegations that appear, when viewed alone, to favor their *Buckman* fraud on the FDA interpretation. The excluded allegations relating to fraud on patients and their physicians are underlined.

> 94. Guidant made the misrepresentations with the intention that the FDA would rely on them in 2001, in deciding to allow the device to continue being implanted in patients, in deciding whether to allow the device to go through a re-approval process after Guidant recalled the device, and in deciding to allow the device to be re-approved; and they made the misrepresentations with the intent that physicians and patients, including the Plaintiff, would rely on them in selecting the Ancure device for implantation. The FDA and physicians and patients in turn relied on the misrepresentations.[1]

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[1] Receipt of the data, first by the FDA and then "in turn" by patients and physicians, is consistent with the regulations, cited and discussed at Pet. 7-8. The data, in the form of MDR reports,

(Continued on following page)

> 95. At all times mentioned herein, and as a result of Guidant's fraudulent conduct, neither the FDA nor the Plaintiff nor his physicians were aware of the true facts with respect to the effectiveness and safety of the commercial use of the Ancure delivery system. The FDA later became partially aware of the facts in its investigation leading to the conviction of EVT/Guidant in 2003. Had the FDA and Plaintiff's physician been aware of the true facts, the device would have been disapproved by the FDA and the Plaintiff's physician would not have used the device to repair plaintiff's aneurysm. Had Plaintiff been aware of these facts, he would not have acquiesced to the use by his physician of the Ancure Device to aid in the repair of the aneurysm.

The exclusions by Respondents starkly confirm that their deception has been deliberate, and continues even now before this Court.

The allegations from paragraphs 94 and 95 disclosed by Respondents relate to intent.[2] All the

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is turned over to the FDA which then turns it over verbatim to the public, with the exception of personal identities. California has long recognized that a fraudulent statement made to one "person" to be communicated to another "person" is actionable under common law. *Lewis v. McClure*, 127 Cal. App. 439, 447, 16 P.2d 166 (3rd Dist. 1932); *Crystal Pier Amusement Co. v. Cannan*, 219 Cal. 184, 186, 25 P.2d 839 (1933).

[2] Intent is always relevant and required in fraud cases; thus Respondents' intentions, including those regarding the FDA, are relevant and necessarily included in the allegations.

allegations in paragraphs 94 and 95 demonstrate that Petitioners' claims are based on the right of patients and physicians to receive honest data, required by federal regulations to be reported to the FDA and then to the public. The public can use that data as they wish to assist them in making medical device selection and implant decisions.

Respondents long ago had more than ample notice of the nature of Petitioners' parallel claims and the arguments supporting those claims.

B. Omitted Facts Demonstrate the Capricious, Unwarranted, and Unnecessary State Law Waiver Ruling

Respondents partially quote the Sixth District's waiver ruling. Opp. 15-16. But they leave out the Sixth District's subsequent and, on its own initiative, succinct statement of California's liberal amendment policy, and that the Sixth District then actually reviewed the trial court's denial of the motion to amend for abuse of discretion, before holding that *Buckman* preempted Petitioners' claims. App. 22.

Respondents also omitted from their discussion of the waiver ruling the following relevant facts:

(1) The three paragraphs of points and authorities previously incorporated by reference in Petitioners' opening Sixth District briefs were fully set out in their

reply briefs, and were the identical points and authorities presented earlier to the trial court (Sixth District reply brief 2);

(2) Petitioners explained in their reply briefs that the incorporation by reference had occurred because the underlying state rule is ambiguous, and pointing out that the cases cited in Respondents' opposition briefs advocating for the waiver decision were easily distinguishable and not relevant (Sixth District reply brief 1-2);

(3) Respondents made reference to and had full access to Petitioners' full points and authorities on the amendment issue, incorporated by reference in Petitioners' Sixth District opening brief. Respondents furthermore argued and provided points and authorities in their support for the trial court's denial of Petitioners' motion to amend, in their Sixth District opposition brief. (Sixth District opposition brief, 23).

Thus, neither the Sixth District nor Respondents were prejudiced by the absence of Petitioners' full argument in their Sixth District opening briefs.

II. RESPONDENTS PROVIDE NO RATIONALE FOR PREEMPTING PETITIONERS' PARALLEL CLAIMS

Petitioners provide ample authorities and rationale for *not* preempting Petitioners' parallel fraud claims, and for granting certiorari. Pet. 16-29. Instead of responding to those authorities and rationale, Respondents chose to falsely assert that Petitioners withheld their parallel claims and arguments until now.

Respondents, in support of preemption, offer only the argument that *Buckman* "has been followed consistently in the lower courts whether the plaintiff refers to such a claim as 'fraud-on-the-FDA' or as a 'parallel claim' under *Riegel*," and cite 6 cases for that argument. Opp. 12. Three of those cases involved alleged failures to disclose to the FDA, the failures to disclose were unsupported by evidence and no parallel fraud on patient violations were alleged. *See, Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919 (5th Cir. 2006); *McCutcheon v. Zimmer Holdings, Inc.*, 586 F. Supp. 2d 917 (N.D. Ill. 2008); *Covert v. Stryker Corp.*, No. 1:08CV447, 2009 WL 2424559 (M.D.N.C. Aug. 5, 2009).

The courts in the fourth and fifth cases actually voice support for parallel claims under *Riegel*. *See, Miller v. DePuy Spine, Inc.*, 638 F. Supp. 2d 1226, 1230 (D. Nev. 2009) ("The Riegel opinion said that such claims, described as state law claims based on 'parallel' duties, might survive express preemption

under §360k, 169 L. Ed. 2d at 906, *and this Court does not disagree*. Mr. Miller, however, has not met his burden to show that there is a genuine issue of fact as to any such 'parallel' claim.") (Emphasis added.); *Link v. Zimmer Holdings, Inc.*, 604 F. Supp. 2d 1174, 1178-79 (N.D. Ill. 2008) ("Link's claims would not be preempted if they were "parallel" to the federal requirements; that is, here, if they offered damages for failure to comply with FDA regulations"; Link alleged no specific regulatory violations and offered no evidence of such violations).

The sixth case cited by Respondents, *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769 (D. Minn. 2009), partially supports Respondents' position. *Riley*, after quoting and interpreting *Buckman* footnote 4, Id. at 776, briefly reviews the *Riegel* exception and finds only a "narrow gap" through which a plaintiff's state-law claim against a medical device manufacturer "can escape" express or implied preemption.

> . . . For a state-law claim to survive, then, the claim must be premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA. Id. at 777.

But see Phillips v. Stryker Corp., No.: 3:09-CV-488, 2010 U.S. Dist. LEXIS 5517 (E.D. Tenn., June 2010) which reviewed but did not follow the *Riley* holding or apply the gap, choosing instead to follow this Court's "last word" in *Riegel*. Id. at 20. ("This Court, however, notes that the Supreme Court's last word on the subject is that '§360k does not prevent a State from

providing a damages remedy for claims premised on a violation of FDA regulations.' *Riegel*, 552 U.S. at 330.")

Petitioners' claims may or may not fit the internally inconsistent *Riley* gap ("violates the FDCA" and "even in the absence of the FDCA"), but they certainly satisfy the *Riegel* preemption exception. The claims allege common law fraud conduct based on violations of FDCA regulations, and are supported by substantial evidence.

III. STATE LAW WAIVER RULING WAS CAPRICIOUS, UNWARRANTED, UNNECESSARY AND BASED ON AN AMBIGUOUS STATE RULE

California Court Rule 8.204(a)(1)(B) requires that appellate briefs "support each point by argument and, if possible, by citation of authority" and Rule 8.204(a)(1)(C) requires that "any reference to a matter in the record [be supported] by a citation to the volume and page number of the record where the matter appears." Neither rule expressly precludes the incorporation of points and authorities presented to the lower court.

The Sixth District's waiver ruling was unnecessary, unwarranted and capricious. The Sixth District nevertheless nullified the waiver ruling, and revived the amendment denial issue, when it subsequently offered its own correct assessment of California's liberal amendment policy, reviewed the trial court's

decision for abuse of discretion and then held that *Buckman* preempted Petitioners' claims – a federal issue.

Deferring to the state courts based on the waiver ruling, in lieu of addressing the significant federal issue, would be inappropriate.

IV. CERTIORARI OF THE *MCGUAN AND JOHNSON* OPINION IS COMPELLING AND WORTHY

Petitioners presented compelling reasons for granting certiorari. Pet. 16-24. Conflicts exist between the Sixth District's *McGuan and Johnson* opinion (App. 1) and the opinions in *Farm Raised Salmon Cases*, 42 Cal. 4th 1077 (2008), cert. den. sub nom., *Albertson's, Inc. v. Kanter*, 129 S. Ct. 896 (2009), as well as with four of this Court's high profile preemption opinions (*Riegel*, *Wyeth*,[3] *Lohr* and *Bates*[4]). The conflict between *Riegel* and *Buckman* created by *McGuan and Johnson* is real and needed to be addressed by Respondents. Respondents failed, however, to address any of the compelling reasons or conflicts involving this Court's opinions.

Respondents do quote an observation by the California Supreme Court in *Farm Raised Salmon Cases* ("[t]he words of section 343-1 clearly and unmistakably evince Congress's intent to authorize

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[3] *Wyeth v. Levine*, 129 S. Ct. 1187 (2009).

[4] *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431 (2005).

states to establish laws that are 'identical to' federal law." Id. at 1090). They then conclude that there is no conflict since "There is no such explicit limitation on the reach of preemption here." Opp. 15. Respondents' conclusion simply ignores *Farm Raised Salmon Cases*' rejection of *Buckman*, in private state claims, and this Court's rationale in *Lohr* and *Bates* (discussed at Pet. 21-23), and they especially ignore this Court's *Riegel* explicit decision that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations." (*Riegel*, *supra*, 128 S. Ct. 999, 1011).

The Sixth District's opinion is worthy of certiorari not because of erroneous factual findings or the misapplication of a properly stated law, but because it held, contrary to *Riegel*, *Lohr*, *Bates*, *Wyeth* and *Farm Raised Salmon Cases*, that Petitioners' parallel claims of fraud based on violations of federal regulations are preempted by *Buckman*.

Certiorari is compelling and worthy.

CONCLUSION

Petitioners therefore ask this Court to grant certiorari, reverse, and remand this case to the California courts for reconsideration of Petitioners' parallel fraud claims.

Respectfully submitted,

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